Report to Congress

Implementation of Section 3507 of the
Patient Protection and Affordable Care Act of 2010

Second Progress Report

Food and Drug Administration

May 2012

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Introduction and Background

In March 2010, President Obama signed into law a comprehensive health reform bill, the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (codified at note following 42 U.S.C. section 18001), and a package of amendments to the Affordable Care Act, the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152).

Subsection 3507(a)[1] of the Affordable Care Act requires the Secretary of Health and Human Services (the Secretary), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (e.g., similar to "Drug Facts" on over-the-counter products) to the promotional labeling or print advertising of such drugs would "improve health care decision making by clinicians and patients and consumers."

Subsection 3507(b) of the Affordable Care Act requires the Food and Drug Administration (FDA) to consider research in the areas of social and cognitive psychology, and to consult drug manufacturers, clinicians, patients and consumers, specifically "experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health."

Finally, subsection 3507(c) of the Affordable Care Act directs FDA to submit a report to Congress outlining its determination under subsection (a). If FDA determines that adding these types of standardized risk/benefit summary statements (or tables), to advertising or promotional labeling for prescription drugs would improve health care decision making, subsection 3507(d) of the Affordable Care Act directs the Agency to promulgate proposed regulations setting forth such requirements.

Currently available research does not provide a sufficient scientific basis to support the required determination. At the time of submission of the first progress report under the Affordable Care Act (March 2011), FDA estimated that the necessary studies, literature review, and consultation with appropriate experts would take roughly three years. These studies are well underway, and an updated timeline for the completion of this work is provided below. If, after these steps are completed, FDA determines that the addition of standardized summary statements would improve health care decision making, FDA will promulgate proposed regulations within two years of its determination. This is the second annual progress report FDA has provided Congress detailing the progress that has been made toward fulfilling the requirements of the law. FDA will report its final determination to Congress in the Fall of 2013.

Steps for Implementation of Section 3507

To implement the provisions of section 3507, FDA will:

- Determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision

[1] Pub. L. No. 111-148, section 3507, 124 Stat. 119, 530 (codified at note following 21 U.S.C. section 352).

making by clinicians and patients and consumers. Because currently available research on the communication of quantitative information in prescription drug promotion is not sufficient to support the required determination, FDA is conducting three studies to address this task.

- ***Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs (Quantitative Study)***. The purpose of this study is to investigate the value of adding quantitative benefit and risk information to DTC advertisements for prescription drugs and to explore a variety of ways to present that information, including numerically and graphically.

- ***Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs (Display Page Study).*** The purpose of this two-part study is to understand how physicians and consumers, respectively, make risk/benefit assessments from labeling and advertising. In particular, we will examine how consumers make such judgments in response to variations in the efficacy presentations in the "display" (first) page of a DTC print and how physicians make similar judgments from professional labeling.

- ***Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements (Format Study).*** The purpose of this study is to systematically examine the type of information that could be presented in a standardized box (i.e., the addition of quantitative and qualitative information in a box format) and the level of efficacy or risk to determine whether and how to add qualitative and quantitative benefit and risk information to the Brief Summary.

We believe that the results from these studies will inform FDA's determination about the usefulness of quantitative summaries of the benefits and risks of prescription drugs in both promotional labeling and print advertising.

- Review all available scientific evidence and research on decision making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities and experts in women's and pediatric health. To do this, FDA has:

    - Contracted with a research firm to conduct a review of available scientific literature (completed February 17, 2012).

    - Presented the results of the literature review and this topic generally to the FDA Risk Communications Advisory Committee (RCAC), allowing us to consult with external experts in the field.

- Evaluate potential methods for, and the utility of, applying a "drug facts box" format for summarizing risks and benefits of products with multiple indications and/or multiple clinical trials. Many products are the subject of multiple pre-market trials conducted by

the drug manufacturer, and the trials may give different, and sometimes conflicting, results. Different trials have different strengths and weaknesses. There is currently no universally accepted method for capturing such information in a standardized quantitative summary format. (FDA's overall conclusions about clinical trials, when approving a drug for one or more indications, takes into account the relative strengths and weaknesses of the trials, as well as an array of additional information, but FDA does not employ the type of summary contemplated by the legislation.)

- Submit to Congress a report that provides (1) the determination by the Secretary under section 3507(a); and (2) the reasoning and analysis underlying that determination.

If FDA determines that it would improve health care decision making by clinicians and patients and consumers, it will promulgate proposed regulations for implementing quantitative summaries of Drug Benefit & Risk Information. The content will be determined after completion of research, review of scientific evidence, and consultations with the RCAC and external experts.

Workplan for Implementation of Section 3507

Completed Work		
First Progress Report to Congress		Completed March 23, 2011
Second Progress Report to Congress		Completed May 2012
Literature Review		Completed February 17, 2012
FDA Risk Communications Advisory Committee (RCAC) Meeting		Completed November 17, 2011
Ongoing Work		
Quantitative Study	Status	Data analysis and report in progress
	Target Date of Completion	June 2012
Display Page Study	Status	Data collection underway
	Target Date of Completion	September 2012
Format Study	Status	OMB approval received February 28, 2012. Pretest data collection in progress.
	Target Date of Completion	April 2013
Third Report to Congress		March 2013
Analysis and determination; preparation of final summary report		April 2012 – September 2013
Final Summary Report to Congress (This report will include the results of FDA's evaluation and determination under section3507(a).)		September 2013
Promulgate proposed regulations (if applicable)		September 2015

Conclusion

Enhancing the public health through improved health care decision making by clinicians, patients, and consumers is a goal shared by both FDA and Congress. FDA appreciates the fact that Congress has recognized that a variety of steps will provide a scientific basis for the appropriate implementation of the requirements of section3507, including a thorough review of all applicable literature, consultation with outside experts in relevant fields, and empirical research. This second progress report updates our timeline for completing the work required to implement section 3507 of the Affordable Care Act and provides the current status of the work. We will continue to keep Congress informed of our progress toward implementing this important law.